Guidelines

for obtaining review by the

Institutional Review Board

Guidelines for Obtaining Review by the Institutional Review Board of the New Jersey Department of Health and Senior Services

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INTRODUCTION AND PURPOSE

One of the many ways the New Jersey Department of Health and Senior Services (DHSS) serves the public and fulfills its mission is through research. Research is defined in the federal regulations as a *systematic investigation designed to develop or contribute to generalizable knowledge*.

Frequently the DHSS conducts research that involves human subjects. The DHSS considers the protection of human subjects as important as the methodology, research findings, or any other component of the research project.

The DHSS has developed policies and procedures to ensure that the rights and welfare of human subjects involved in research are protected and consistent with Federal regulations (45 CFR Part 46). The Office of Protection from Research Risks (OPRR), National Institutes of Health, is responsible for developing and enforcing Federal regulations on human subjects research funded by the U.S. Department of Health and Human Services. Policies, guidelines and regulations from OPRR provide the structure for DHSS review and approval of human subjects research.

A major component of the process for ensuring the protection of human subjects in DHSS research is the function of the Institutional Review Board (IRB). Members of the IRB are appointed by the Commissioner of DHSS. Some of the members must be from outside of the agency. The IRB approves, disapproves or defer decisions on research protocols using the following criteria.

- The design of the study is consistent with sound scientific principles and ethical norms;
- The protocol meets the criteria necessary for approval;
- The necessary elements of informed consent have been fulfilled; and
- Additional appropriate safeguards have been provided if potentially vulnerable subjects are to be studied.

The research protocol must be approved by the IRB (unless the research is exempt from IRB review) before human subjects can begin participation. The IRB also conducts continuing review of each approved protocol at least yearly, although the IRB may request more frequent evaluations. The IRB may modify, suspend or terminate approval of research that has been associated with serious harm to subjects or is not being conducted in accord with the IRB's decisions, stipulations, and requirements.

Issues that researchers and managers must consider when determining the need for human subjects review includes:

- Which projects constitute research involving human subjects;
- Which projects require review by an IRB; and
- Which projects are exempt from IRB review.

The purpose of this document is to acquaint researchers and managers with the issues and policies related to the human subject review process.

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KEY DECISIONS ABOUT HUMAN SUBJECTS REVIEW REQUIREMENTS

In general, any study that is conducted by DHSS, by outside investigators in collaboration with DHSS, or by outside investigators using DHSS data is potentially subject to review and approval by the DHSS Institutional Review Board (IRB). However, not all studies meet the criteria for IRB review.

This section covers the process for determining the need for human subjects review. The decision-making process is divided into three key decision steps:

Step 1 **Does the project involve human subjects?**

Step 2 **Is the project research?**

Step 3 **Is the project exempt from IRB review?**

Each step is outlined in a flow diagram that is followed by a description.

STEP 1 DOES THE PROJECT INVOLVE HUMAN SUBJECTS?

The DHSS investigator and/or the DHSS staff responsible for the data should determine whether the project involves human subjects.

1.A Does the Project Involve Obtaining Private Information About Living Individuals?

Private information is defined as (1) information which has been provided for specific purposes by an individual which (s)he can reasonably expect will not be made public (e.g., a medical record), or information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.

1.B Is the Private Information Individually Identifiable?

Individually identifiable means that private information is recorded in such a way that (1) the identity of the subject is or may be ascertained by the investigator, or (2) the identity of the subject may readily be inferred from the information obtained.

1.C Does the Project Involve Intervention or Interaction with Living Individuals for the Purpose of Obtaining Data?

Intervention includes physical procedures by which data are collected, such as venipuncture, and manipulations of the subject or the subject's environment. Interaction includes communication or interpersonal contact with the subject, the subject's next of kin, or the subject's physician or hospital.

1.D Does the Project Involve Obtaining of Death Certificate Data With Personal Identifiers and Cause of Death?

Under New Jersey regulations, death certificates that include cause of death will not be released to researchers unless their research has been approved by an IRB.

STEP 2 IS THE PROJECT RESEARCH (i.e., a systematic investigation designed to develop or contribute to generalizable knowledge)?

If the project involves human subjects, the DHSS investigator should then determine whether the project constitutes research. The main criterion for determining whether a project is research is the purpose of the activity. The project is research if its primary purpose is to gain knowledge that is generalizable to other populations and/or other settings. Examples of research projects include studies of the effects of behavior modification strategies on health outcomes, surveys of health care behaviors and practices in a sample of the population, and studies of exposed and unexposed populations living near hazardous waste sites. In contrast, the project is *not* research if it is primarily being conducted to gain knowledge and information that can be immediately used to benefit the participants. Note that if at any point the purpose of the project changes so that the project becomes a systematic investigation designed to develop or contribute to generalizable knowledge, the investigator must consult the DHSS IRB to determine the need for IRB review.

2.A Is the Project Surveillance Involving Only the Usual Data Collection Systems for Public Health?

Surveillance refers to the regular ongoing collection and analysis of health-related data (in terms of time, place, person). If the surveillance activity is conducted solely to monitor the frequency of occurrence and distribution of disease or health condition in the population, it is not considered research. Such activities are the public health equivalent of a private physician checking the vital signs of an individual patient. Examples of nonresearch surveillance projects include (1) the routine reporting of cases of notifiable diseases by State health departments to the Morbidity and Mortality Weekly Report and (2) other routine monitoring of the occurrence of diseases and conditions in a population for the purpose of detecting conditions for which research is or may be needed, or to determine whether public health action is needed to decrease the incidence of these diseases and conditions.

If, on the other hand, surveillance activity is being conducted, *in whole or in part*, to gather data and obtain knowledge from which to generalize to other populations and/or settings, the project is considered research. An example is a study for the purpose of determining why certain groups are at higher risk of disease than others.

2.B Is the Project an Evaluation to Assess the Success of a Specific Program?

Evaluations of ongoing public health programs may or may not constitute research. A program evaluation is not considered research if the purpose of the evaluation is to assess the success of a specific program in achieving its objectives and is part of normal public health program operations, analogous to the ongoing monitoring by surgeons of their patients so that corrective action can be taken to improve the quality, effectiveness, and cost-effectiveness of the care they provide. If, on the other hand, the purpose of a program evaluation is to develop or contribute to generalized knowledge, the project is considered research. However, some evaluation research may be exempt from IRB review (see Step 3).

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2.C Is the Project an Investigation Both to Determine the Cause and/or Extent of a Particular, Current Health Problem in the Community and to Develop Plans for its Control?

OPRR regulations specify that the regulations are not intended to interfere with the ability of a physician to provide emergency medical care. It logically follows that the regulations must not impair the ability of DHSS staff and other public health officials to investigate and respond to public health emergencies. When responding to a public health emergency, DHSS considers such investigations as the public health equivalent of individual doctor-patient situations in which the community (as patient) presents with a health problem, which DHSS and other health agencies (as physician) are expected to diagnose and control (treat) without delay. Thus, an investigation is *not* research if its primary purpose is to determine the cause and/or extent of a current community health problem and to develop plans for its control.

Specific examples of nonresearch investigations include the prompt investigation of an outbreak of gastrointestinal illness in a community or an investigation of the exposure of a group of people to a cloud of toxic gas. These nonresearch investigations may include interviews with affected or potentially affected subjects to obtain medical histories, medical and health records reviews, physical examinations, and routine medical tests (e.g., blood tests, chest radiographs, and electrocardiograms) to determine the existence and nature of their health problems.

2.D If the project is not considered research and IRB review is not necessary for the project, adequate care should still be taken to protect the rights and welfare of any individuals involved in the project. For example, if the project involves obtaining private, individually identifiable information about living individuals for the purpose of obtaining data, measures should be taken which will ensure protection of those individuals. Potential participants in a project should know that their participation is voluntary before they are asked questions or specimens are taken from them. Although the activities described above are not considered research *per se*, investigators should consider whether the use of consent forms would help protect human subjects.

The IRB is always be available to provide guidance for determining if IRB review is required. Even if IRB review is not required, the project may still request IRB review to address ethical questions posed by the investigator or reviewers, or because of potential controversy or publicity associated with the project.

STEP 3 IS THE PROJECT EXEMPT FROM IRB REVIEW?

Certain research activities involving human subjects are exempt from IRB review. However, if the human subjects in the project are pregnant women, children, or prisoners, these exemptions do not apply. *All* of the research activities in a project which involve human subjects must be exempt in order for the project as a whole to be exempt from IRB review. If only one activity is not exempt, the project is not exempt. Investigators will submit protocols to the IRB to determine if they are exempt. The IRB determines exempt status based on the following criteria:

3.A Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods, is exempt from IRB review.

3.B Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior is exempt from IRB review *unless:*

(a) information is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

However, research normally not exempt from IRB review according to criteria (a) and (b) above may be exempt *if*: (a) the human subjects are elected or appointed public health officials or candidates for public offices *or* (b) Federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

3.C. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens is exempt from IRB review if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

3.D Research and demonstration projects are exempt from IRB review if they are conducted by the DHSS or subject to the approval of the DHSS and are designed to study, evaluate or otherwise examine:

(a) public benefit or service programs;

(b) procedures for obtaining benefits or services under those programs;

(c) possible changes in or alternatives to those programs or procedures; or

(d) possible changes in methods or levels of payment for benefits or services under those programs.

3.E Taste and food quality and consumer acceptance studies are exempt from IRB review if (a) wholesome foods without additives are consumed or (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Even if the IRB determines that a study is exempt from IRB review, the project may still request IRB review. This might be done to address ethical questions posed by the investigator or reviewers, or it might done because of potential controversy or publicity associated with the project.

To apply for IRB review, consult the companion document: "Procedures for Obtaining Review by the Institutional Review Board of the New Jersey Department of Health and Senior Services."